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105TH CONGRESS
2D SESSION

H. R. 3462

To amend the Federal Food, Drug, and Cosmetic Act to require notification of recalls of drugs and devices, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 12, 1998

Mr. SHAYS (for himself and Mr. KUCINICH) introduced the following bill; which was referred to the Committee on Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require notification of recalls of drugs and devices, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Drug and Device Recall Reporting Act of 1998''.

SEC. 2. RECALLS.

Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end the following:

"SEC. 564. NOTIFICATION OF RECALLS.

''(a) NOTIFICATION TO CUSTOMERS.—A pharmacy that receives notice from a recalling firm regarding a Class I or Class II recall of a drug or device shall provide notification about the recall to customers that received the drug or device as follows:

''(1) In the case of a drug or device dispensed by the pharmacy to customers on the prescription of a licensed practitioner, by providing, at a minimum, written notification to each of the customers.

''(2) In the case of another drug or device, by public display in the pharmacy of a notice regarding the recall.

''(b) CIVIL PENALTY.—Any pharmacy that violates subsection (a) shall be liable to the United States for a civil penalty in an amount not to exceed $10,000 for each such violation.

''(c) DEFINITIONS.—In this section:

''(1) RECALLING FIRM.—The term 'recalling firm' means—

''(A) a recalling firm as defined in subpart A of part 7 of title 21, Code of Federal Regulations ; or

''(B) a person subject to an order issued under section 518(e)(1).''.

"(2) CLASS I OR CLASS II.—The term Class I or Class II refers to the designation given recalls in subpart A of part 7 of title 21, Code of Federal Regulations.

"(3) RECALL.—The term 'recall' means—

"(A) a recall as defined in subpart A of part 7 of title 21, Code of Federal Regulations; or

"(B) a recall under section 518(e).

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